NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. S HACKETT MARKETING LLC d/b/a JUST ENHANCE, et al., Defendants.	Civil Action No. 17-04911 (MAS) (TJB) **MEMORANDUM OPINION**

SHIPP, District Judge

This matter comes before the Court on Plaintiff United States of America's (the "Government") Motion for Default Judgment. (ECF No. 14.) Defendants S Hackett Marketing LLC d/b/a Just Enhance ("Just Enhance"), R Thomas Marketing LLC ("R Thomas Marketing"), Shawn Hackett, president and owner of Just Enhance ("Hackett"), and Roger Thomas, president and founder of R Thomas Marketing ("Thomas") (collectively, "Defendants") failed to file an answer to the Complaint (ECF No. 1), any responsive motion, opposition to the instant motion, or to appear in this action. The Court has carefully considered the Government's motion and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons stated below, Plaintiff's motion for default judgment is granted.

I. Background[1]

The Government's action stems from Defendants' distribution of sexual enhancement drugs (the "Illicit Drugs") in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"). (*See generally id.*) Defendants market, sell, and distribute Illicit Drugs that purportedly increase sexual function and manage hundreds of websites through which the drugs are sold. (Compl. ¶¶ 1-8, ECF No. 1.) The Food and Drug Administration ("FDA") tested the Illicit Drugs and detected sildenafil, which is an ingredient in Viagra, an FDA-approved prescription drug used to treat erectile dysfunction. (*Id.* ¶ 10.) Sildenafil may create significant health risks to those with certain medical issues, but the labelling does not disclose that the Illicit Drugs contain this ingredient. (*Id.*)

In January and March 2015, the FDA made undercover purchases of various Illicit Drugs from Defendants' websites and on July 31, 2015, the FDA sent Defendants a Warning Letter that informed them that they were distributing "unapproved new drugs and misbranded drugs in violation of the FDCA and its regulations." (*Id.* ¶ 33.) Defendants failed to respond. In January 2016, Defendants recalled certain Illicit Drugs and Thomas told the FDA that the recalled drugs would be sent to Hackett in New Jersey. (*Id.* ¶ 35.) In that same month, the FDA inspected the business address of R Thomas Marketing, and during the inspection, Thomas told investigators that he would cease distribution of the Illicit Drugs. (*Id.* ¶ 36.) During the ongoing inspection, however, the FDA made an undercover purchase of one of the Illicit Drugs. (*Id.*) In February 2016, Defendants' consulting firm told the FDA that Defendants terminated fifty-seven websites

[1] "[D]efendants are deemed to have admitted the factual allegations of the Complaint by virtue of their default, except those factual allegations related to the amount of damages." *Doe v. Simone*, No. 12-5825, 2013 WL 3772532, at *2 (D.N.J. July 17, 2013) (citing 10A Charles A. Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2688 (3d ed. 1998 and Supp. 2013)). Accordingly, the Court summarizes the facts set forth in the Complaint.

and eight remained active with a posted recall notice. (*Id.* ¶ 37.) In June 2016, the consulting firm, on Defendants' behalf, told the FDA that Defendants had not sold the Illicit Drugs since November 2015; however, in July 2016, the FDA made another round of undercover purchases of the Illicit Drugs. (*Id.* ¶ 38.) Thomas and Hackett represented on an August 2016 telephone call with the FDA that Defendants had not distributed the Illicit Drugs since November 2015. (*Id.* ¶ 40.) Yet, in September 2016: (i) R Thomas Marketing sent an e-mail message to an FDA undercover account soliciting a sale, and the FDA purchased some Illicit Drugs; and (ii) Hackett and Just Enhance sent a solicitation e-mail message to another FDA undercover account that contained a link to purchase Illicit Drugs on a website registered to Thomas. (*Id.* ¶ 41.) Finally, in December 2016: (i) Hackett and Just Enhance sent another e-mail solicitation to an FDA undercover account and in response, the FDA made an undercover purchase of Illicit Drugs, shipped from Hamilton, New Jersey; and (ii) R Thomas Marketing sent a solicitation e-mail to an FDA undercover account, and the FDA purchased Illicit Drugs. (*Id.* ¶ 42).

On July 5, 2017, the Government filed a Complaint against Defendants that seeks a permanent injunction pursuant to the FDCA 21 U.S.C. § 332(a) to permanently enjoin Defendants from violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs that are neither approved under 21 U.S.C. § 355, nor exempt from approval; and violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) and (a). (Compl. ¶ 1.)

All Defendants were served: R Thomas Marketing LLC and Roger Thomas on August 28, 2017 (Affs. of Service, ECF Nos. 7, 8); S Hackett Marketing LLC and Shawn Hackett on

September 16, 2017 (Affs. of Service, ECF Nos. 9, 10). R Thomas Marketing LLC's and Thomas's answers to the Complaint were due by September 18, 2017, and S Hackett Marketing LLC's and Shawn Hackett's answers to the Complaint were due by October 10, 2017; however, none of Defendants responded. Accordingly, on September 20, 2017 and October 11, 2017, the Government requested entry of default. (ECF Nos. 11, 12.) The Government subsequently obtained a Clerk's entry of default against each Defendant. The Government now moves for final entry of default judgment. (ECF No. 14.)[2]

II. Legal Standard

Rule 55(b) of the Federal Rules of Civil Procedure allows for the entry of default judgment against a party who has failed to plead or otherwise defend claims asserted against it after default has been entered by the Clerk of Court. Fed. R. Civ. P. 55(b). "[D]efendants are deemed to have admitted the factual allegations of the Complaint by virtue of their default, except those factual allegations related to the amount of damages." *Doe v. Simone*, No. 12-5825, 2013 WL 3772532, at *2 (D.N.J. July 17, 2013) (citing 10A Charles A. Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2688 (3d ed. 1998 and Supp. 2013)).

Prior to entering default judgment, the Court must determine whether it has subject matter jurisdiction over the claims asserted and personal jurisdiction over the parties. *Mark IV Transp. & Logistics v. Lightning Logistics, Inc.*, No. 16-3572, 2017 WL 3668946, at *4 (3d Cir. Aug. 25, 2017) (citing *Prudential Ins. Co. of Am. v. Bramlett*, No. 08-119, 2010 WL 2696459, at *1 (D.N.J. July 6, 2010)). Further, the Court must determine "whether the moving party's complaint establishes a legitimate cause of action." *La. Counseling and Family Servs., Inc. v.*

[2] In its briefing, the Government represented that it received correspondence from Thomas on behalf of S Hackett Marketing and R Thomas Marketing confirming he was served with the summons and Complaint and he and the other two defendants would not challenge the action. (Pl.'s Moving Br. 1 n.1, ECF No. 14-1.)

Makrygialos, LLC, 543 F. Supp. 2d 359, 365 (D.N.J. 2008) (citation omitted). If these initial requirements are met, then the Court must consider three factors to determine whether entry of a default judgment is appropriate: "(1) prejudice to the plaintiff if default is denied, (2) whether the defendant appears to have a litigable defense, and (3) whether defendant's delay is due to culpable conduct." *Chamberlain v. Giampapa*, 210 F.3d 154, 164 (3d Cir. 2000) (citing *United States v. $55,518.05 in U.S. Currency*, 728 F.2d 192, 195 (3d Cir. 1984)).

III. Analysis

A. Threshold Considerations

1. Jurisdiction

Section 332(a) of the FDCA, titled "Injunction proceedings," provides that "[t]he district courts of the United States . . . shall have jurisdiction, for cause shown[,] to restrain violations of [21 U.S.C. § 331]." 21 U.S.C. § 332(a). The Court, therefore, exercises subject matter jurisdiction over the Government's federal claims pursuant to 28 U.S.C. § 1331.

In addition, the Court has personal jurisdiction over Defendants. Just Enhance operates out of this state, where it distributes and receives the Illicit Drugs from multiple New Jersey locations. (Compl. ¶ 4.) Hackett, president and owner of Just Enhance, receives and ships the Illicit Drugs and manages hundreds of websites, websites used to sell the Illicit Drugs, within New Jersey. (*Id.* ¶¶ 5, 8.) Hackett was personally served with process in New Jersey.[3] *See* Fed. R. Civ. P. 4(e); (Aff. of Service, ECF No. 9). Moreover, Hackett accepted service on behalf of Just Enhance as its owner. *See* Fed. R. Civ. P. 4(h); (Aff. of Service, ECF No. 10). R Thomas Marketing operates out of a Bronx, New York address but distributes sexual enhancement drugs to Hackett in New Jersey. (*Id.* ¶ 6.) Thomas, president and founder of R Thomas Marketing,

[3] The facts in the Complaint suggest, but do not explicitly state, that Hackett is domiciled in New Jersey; therefore, the Court turns to the above rule to find personal jurisdiction.

handles day-to-day shipping and receiving, manages websites, and provides customer service. (*Id.* ¶ 7.) Thomas was personally served pursuant to Federal Rule of Civil Procedure 4(e)(2)(A), and through Thomas, R Thomas Marketing was served pursuant to Federal Rule of Civil Procedure 4(h)(1)(B). (*See* ECF Nos. 7-10.) This action arises out of Thomas and R Thomas Marketing's marketing, sale, and distribution of the Illicit Drugs to locations in New Jersey; accordingly, the Court has specific jurisdiction over Thomas and R Thomas Marketing. *See Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 96 (3d Cir. 2004) (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985)) ("Specific jurisdiction over a defendant exists when that defendant has 'purposefully directed his activities at residents of the forum and the litigation results from alleged injuries that arise out of or relate to those activities.'").

2. Whether the Complaint Establishes a Legitimate Cause of Action

a. Distribution of Unapproved New Drugs, 21 U.S.C. § 331(d)

A "drug" under the FDCA is a substance "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C). An intended use can be determined in any relevant manner, including through its labeling, *see* 21 C.F.R. § 201.128, which includes "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). Labeling need not be physically attached to the product, but instead includes materials that are textually relevant. *See Kordel v. United States*, 335 U.S. 345, 349-50 (1948).

A "new drug" is any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate

the safety and effectiveness of drugs, as safe and effective[4] for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). To introduce, or deliver for introduction, a "new drug" into interstate commerce, the FDA must approve a new drug application ("NDA") or an abbreviated new drug application ("ANDA"), or the new drug must be exempt from the approval process pursuant to an investigational new drug application ("IND"). 21 U.S.C. § 355(a), (b), (j), and (i). Otherwise, a person who introduces or delivers for introduction into interstate commerce an unapproved new drug violates the Act. 21 U.S.C. § 331(d).

The Government has stated a legitimate cause of action, as it has alleged that the Illicit Drugs are "drugs" within the meaning of the FDCA. Based on their labeling, which includes "package inserts that accompany the products and Defendants' websites from which the products may be ordered," it is evident that "Defendants' sexual enhancement products are intended for use to cure, mitigate, treat, and/or prevent various diseases and to affect the structure or any function of the body of man." (Compl. ¶¶ 13-14.) Defendants' labeling makes at least thirty-two structure and function claims. (*See, e.g.*, Compl. ¶¶ 14A-14FF.)[5] Further, the Government has alleged that the Illicit Drugs are unapproved New Drugs.

> FDA searched the literature and found no adequate and well-controlled studies demonstrating substantial evidence of safety and effectiveness for any of

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[4] For a drug to be "generally recognized as safe and effective" ("GRAS/E"), it must (1) have substantial evidence of safety and effectiveness as demonstrated through adequate and well-controlled clinical studies; (2) the studies on which a claim of GRAS/E is based must be published in the scientific literature so that they are made generally available to the community of qualified experts; and (3) there must be a consensus of opinion among qualified experts, which is based on the published studies, that the drug is safe and effective for its labeled indications. If it is an over-the-counter ("OTC") drug, it must comply with a monograph established under an FDA regulation. 21 U.S.C. § 355(d); 21 C.F.R. § 330.1.

[5] For example, the labelling for "Africa Black Ant" states that its indications are "premature ejaculation, impotence, . . . myasthenia of limbs, tinnitus, . . . prostatitis." (Compl. ¶ 14C.)

> Defendants' sexual enhancement products. Therefore, Defendants' sexual enhancement drugs are "new drugs," because they are drugs within the meaning of 21 U.S.C. § 321(p) and they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Moreover, Defendants' sexual enhancement drugs do not conform to any OTC drug monograph. FDA representatives searched agency records and determined that Defendants do not have an approved NDA or ANDA or an effective IND for any of their drugs.

(Compl. ¶¶ 18-19.)

b. Distribution of Misbranded Drugs, 21 U.S.C. §§ 352(f)(1) and 352(a)

i. 21 U.S.C. § 352(f)(1)

"Misbranded" drugs under 21 U.S.C. 352(f)(1) have labeling that does not contain "adequate directions for use" and are not exempt from this requirement. 21 C.F.R. § 201.5. "[A]dequate directions for use" are "directions under which the layman can use a drug safely and for the purpose for which it is intended." *Id.* The Illicit Drugs are unapproved new drugs and accordingly, are required to contain adequate instructions for use. (Compl. ¶ 23 (citing 21 C.F.R. §§ 201.100(c)(2), 201.115).) Additionally, prescription drugs, by their definition, cannot have adequate directions for layperson use. 21 U.S.C. § 353(b)(1)(A). Because: (i) the Illicit Drugs contain sildenafil, which has possible detrimental effects; and (ii) "medical expertise and special clinical assessments are needed to diagnose and determine appropriate therapeutic interventions for many of their intended uses, including erectile dysfunction, impotence, and prostatitis," the Illicit Drugs are prescription drugs. (Compl. ¶ 25.) Accordingly, no "adequate direction for use" can be created for the Illicit Drugs. (*Id.*) Finally, any adequate directions would be based on expansive scientific testing to produce both animal and clinical data; here, no such testing has been performed. (*Id.* ¶ 26.) Accordingly, the Government has sufficiently alleged that because

the Illicit Drugs fail to bear adequate directions for use, they are "misbranded" drugs pursuant to 21 U.S.C. 352(f)(1).

ii. 21 U.S.C. 352(a)

If a drug's "labeling is false or misleading,"[6] the drug is misbranded pursuant to 21 U.S.C. § 352(a). The Government asserts that "[t]he labeling for Defendants' sildenafil-containing drugs is false and misleading because it does not declare that the drugs contain sildenafil or reveal the consequences that may result from using a drug containing sildenafil." (Compl. ¶ 29.) Accordingly, the Government has sufficiently alleged the Illicit Drugs are "misbranded" drugs pursuant to 21 U.S.C. § 352(a).

c. Distribution in Interstate Commerce, 21 U.S.C. §§ 331(a) and (d)

The Complaint contains various allegations that demonstrate the Illicit Drugs were introduced into interstate commerce. In January 2016, during an inspection at R Thomas Marketing, Thomas "told FDA investigators that Defendants distribute their sexual enhancement drugs to customers across the United States." (Compl. ¶ 31.) In July 2016, Just Enhance shipped various Illicit Drugs from New Jersey to Maryland, and in September 2016, R Thomas Marketing shipped Illicit Drugs from New York to Maryland. (*Id.*) Accordingly, "[t]hese shipments constitute the introduction or delivery for introduction, or causing the introduction or delivery for introduction, into interstate commerce of unapproved new drugs and misbranded drugs in violation of 21 U.S.C. § 331(a) and (d)." (*Id.*) The Complaint, therefore, states a legitimate causes of action, and the Court next considers the *Chamberlain* factors.

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[6] When determining whether labeling is "misleading," considerations include "representations made or suggested," and "the extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling." 21 U.S.C. § 321(n).

B. *Chamberlain* Factors

1. Prejudice to the Government if Default is Denied

"As to the first factor, '[w]hen a defendant fails to respond to a plaintiff's claims, the plaintiff will be prejudiced absent a default judgment because [the] plaintiff will be left with no other means to vindicate his or her claims.'" *United States v. DiPiazza*, No. 16-518, 2016 WL 7015625, at *2 (D.N.J. Nov. 30, 2016) (quoting *United States v. Vo*, No. 15-6327, 2016 WL 475313, at *3 (D.N.J. Feb. 8, 2016)). In this case, Defendants failed to participate in the case in any way; thus, the Government will suffer prejudice if default is denied. The Court, therefore, finds that the first *Chamberlain* factor weighs in favor of entering default judgment.

2. Whether Defendants Have a Litigable Defense

"A . . . defense[] will be deemed meritorious when the allegations of the pleadings, if established at trial, would . . . constitute a complete defense." *Poulis v. State Farm Fire and Cas. Co.*, 747 F.2d 863, 869-70 (3d Cir. 1984). Here, Defendants failed to raise any defenses for the Court's consideration because Defendants failed to respond. *See Vo*, 2016 WL 475313, at *3 (noting that "the [c]ourt cannot consider [d]efendant's defenses if any exist because [d]efendant failed to respond to this action"); *Prudential Ins. Co. of Am. v. Taylor*, No. 08-2108, 2009 WL 536403, at *1 (D.N.J. Feb. 27, 2009) (stating that "because [defendant] has not answered or otherwise appeared in this action, the Court was unable to ascertain whether [defendant] has any litigable defenses"). Thus, the second *Chamberlain* factor indicates that default judgment is warranted.

3. Whether Defendants' Delay is Due to Culpable Conduct

In considering whether a default was the result of a defendant's culpable conduct, the Court asks, "whether [defendant] acted willfully or in bad faith." *Feliciano v. Reliant Tooling*

Co., LTD., 691 F.2d 653, 657 (3d Cir. 1982). Here, the Government served Defendants with its Complaint on January 17, 2017 and Defendants failed to respond with any filing or submission to the Court. While Defendants' complete inaction "may not necessarily reflect bad faith, at the very least it reflects willful conduct." *DiPiazza*, 2016 WL 7015625, at *5. The final *Chamberlain* factor, therefore, weighs in favor of the Court's entry of default judgment.

C. Permanent Injunction

To obtain injunctive relief pursuant to 21 U.S.C. § 355(a), the Government must show that (1) Defendants violated the FDCA and (2) "there is a reasonable likelihood that the purported violations will recur." *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 571 (D.N.J. 2004) (citing *United States v. W.T. Grant, Co.*, 345 U.S. 629, 633 (1953); *United States v. Barr Labs., Inc.*, 812 F. Supp. 458, 485-86 (D.N.J. 1993)); *see also id.* at 486 (quoting *United States v. Spectro Foods Corp.*, 544 F.2d 1175, 1181 (3d Cir. 1976)) ("Preliminary injunctions based on violations of [the FDCA] 'do not require a showing of immediate and irreparable injury.'"). The Court finds that Defendants violated the FDCA and that it is "reasonabl[y] likel[y]" that the conduct "will recur." *Lane Labs-USA, Inc.*, 324 F. Supp. 2d at 571. After receiving a Warning Letter, Defendants were on notice that their behavior violated the FDCA, but they did not respond to the correspondence. Defendants made multiple representations to the FDA that they had ceased distribution of Illicit Drugs, and yet, even during an ongoing recall, Defendants still solicited sales via e-mail correspondence and the FDA made multiple undercover purchases.

IV. Conclusion

For the reasons set forth above, the Government's motion for default judgment is granted.

An order consistent with this Memorandum Opinion will be entered.

s/ Michael A. Shipp
MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE

Dated: August 30, 2018